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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

WELLS, LAUREN Q

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 11/22/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/841,078

Applicant(s)

LACHARRIERE ET AL.

Examiner

Lauren Q Wells

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-10 and 12-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-10 and 12-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 08/580,291.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>10</u> . | 6) <input type="checkbox"/> Other: |

Art Unit: 1617

DETAILED ACTION

Claims 1, 3-10, 12-21 are pending. The Amendment filed 10/15/02, Paper No. 9, cancelled claims 2 and 11, amended claims 1 and 10, and amended paragraphs 7, 11, 12, 13, 20, 24, and 26 in the specification.

The Terminal Disclaimer filed 10/15/02, is sufficient to overcome the double patenting rejection over US Patent No. 6,060,061 in the previous Office Action. Because the present application is a divisional of co-pending application 09/391,399, which is a continuation of US 5,993,833, which is a divisional of US 5,658,581, a terminal disclaimer is not required to obviate the rejection over the '581 patent. Thus, this rejection is hereby withdrawn.

Request for Continued Examination

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/15/02 has been entered.

Response to Arguments

Applicant's arguments with respect to claims 1-18 have been considered but are moot in view of the new ground(s) of rejection. However, to the extent that the arguments may be relevant to the instant rejection, the Examiner will address them.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

Art Unit: 1617

pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of irritant side-effects, does not reasonably provide enablement for preventing irritant side-effects. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

There are several guidelines when determining if the specification of an application allows the skilled artisan to practice the invention without undue experimentation. The factors to be considered in determining what constitutes undue experimentation were affirmed by the court in *In re Wands* (8 USPQ2d 1400 (CAFC 1986)). These factors are the quantity of experimentation; the amount of direction or guidance presented in the specification; the presence or absence of working examples; the nature of the invention; the state of the prior art; the level of skill of those in the art; predictability or unpredictability of the art; and the breadth of the claims.

The disclosure of the present invention is directed to a composition that treats or prevents irritant side-effects as set forth in independent claims 1, 10, and 19-21. A skilled practitioner in the art using the teachings of US Patent Nos. 6,416,760; 6,365,623; 6,262,050 would be motivated to reduce or eliminate irritant side-effects. However, preventing irritant side-effects is inconsistent with what is known in the art since (1) reduction of irritant side-effects indicates that irritant side-effects is decreased, but not prevented; and (2) elimination of irritant side-effects indicates that symptoms of irritant side-effects may occur. Furthermore, prevention of irritant side-effects indicates that the subject never experiences any characteristics associated with irritant side-effects. Hence, the amount of guidance present in the specification, the absence of

Art Unit: 1617

data indicating that the symptoms of irritant side-effects do not occur, and the state of the prior art indicating that treatment of irritant side-effects is possible, all indicate that treatment, not prevention of irritant side-effects is possible.

The amount of guidance necessary to perform Applicant's invention would result in undue experimentation because the skilled artisan would be forced to randomly test numerous conditions and amounts of interleukin-1 antagonists, TNF-alpha antagonists, and combinations thereof in composition to determine what compositions prevent irritant side-effects. Hence, the amount of guidance present in the specification fails to present the necessary instruction such that one can readily determine the appropriate composition of claims 1, 10, and 19-21.

Note: The Examiner reviewed Applicant's specification, but noted that the data does not indicate prevention of irritant side-effects.

Substituting the term "substantially inhibit" or "treat" for the term "prevent" in claims 1, 10 and 19-21, will overcome this rejection.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8-10, 12-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(i) The term "capable of" in claims 10 (line 10), 12 (line 2) is vague and indefinite, as it has been held that the recitation that an element is 'capable of' performing a function is not a positive limitation but only requires the ability to so perform that function. It does not constitute a limitation in any patentable sense. In re Hutchison, 69 USPQ 138.

Art Unit: 1617

(ii) Claims 8 and 17 are rejected for the use of improper Markush groups. See MPEP 2173.05(h) for examples of proper conventional or alternative Markush-type language (e.g., “. . .selected from the group consisting of. . .and . . .”). The Markush language is confusing because beginning on line 4 of the claims, the term “and” and the term “and/or” begin to appear between different members of the Markush group. It is not clear if these members and their combinations are somehow distinct from those which proceed line 4, as the proceeding Markush members are only separated by commas.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3-10, 12-18 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parker et al. (5,039,695) in view of Farnag et al. (5,643,584).

Parker et al. teach a method of using aryl or heteroaryl 1 alkyl pyrrole 2 carboxylic acid compounds in the treatment of interleukin 1 mediated conditions, such as psoriasis, wherein the heteroaryl-1-aryl-pyrrole-2-carboxylic acid is a heterocycle and is a nitrogen compound having at least one benzene ring. Disclosed is a cream comprising 4% of an interleukin-1 antagonist (the Pyrrole 2 carboxylic acid), cetyl alcohol (alcoholic solution agent which produces irritant), glycerol monostearate PEG 40, diglycol stearate, polyethylene glycol 400, and purified water. The interleukin-1 antagonists are disclosed as comprising 0.01-15% of the composition. Oil in water emulsions, oily suspensions, aqueous suspensions, and others are disclosed as forms of the

Art Unit: 1617

composition. The reference lacks an agent which produces an irritant. See Col. 1, line 55-Col. 3, line 20; Col. 7, line 51-Col. 12, line 65.

Farnag et al. teach aqueous gel retinoid dosage forms. It is disclosed that retinoids have found clinical utility in the treatment of psoriasis. Antibiotics and antifungals are disclosed for use in compositions with retinoids. The Examiner respectfully points out that microbes and fungi are parasites. Thus, antibiotics and antifungals are antiparasites. See Col. 1.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add the retinoids of Farnag et al. to the composition of Parker et al. because of the expectation of achieving an additive effect of the retinoids and the interleukin-1-antagonist in treating psoriasis and because it is obvious to combine individual compositions taught to have the same utility to form a new composition for the very same purpose. In re Kerkhoven, 626 F.2d 846, 205 USPQ 1069 (CCPA 1980).

Additional Comments

Claims 19-20 are free of the art. These claims would be allowable if Applicant substitutes the term "substantially inhibit" or "treat" for the term "prevent" in these claims.

Response to Arguments

Applicant argues, "This present invention relates to the use of a histamine antagonist, an interleukin-1-antagonist and/or a TNF-alpha antagonist in a cosmetic, pharmaceutical or dermatological composition for topical application". This argument is not persuasive, as it is not commensurate in scope with the instant independent claims, which are not method claims, but are product (composition) claims, and which do not recite histamine antagonists.

Based on the new grounds of rejections, all other arguments are moot.

Art Unit: 1617


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is (703) 305-1878. The examiner can normally be reached on M-F (7-5:30), with alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (703)305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

lqw
November 8, 2002


SREENI PADMANABHAN
PRIMARY EXAMINER
11/16/02